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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/601,607 | 06/24/2003 | Gregory S. Hamilton | 054707-1225 | 8963 |

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GUILFORD PHARMACEUTICALS C/O
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3000 K STREET, NW
WASHINGTON, DC 20007-5143

EXAMINER

CHANG, CELIA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1625

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,607

Applicant(s)

HAMILTON ET AL.

Examiner

Celia Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 72-85 is/are pending in the application.
- 4a) Of the above claim(s) 78, 79 and 81-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 72-77 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 72-74, 75 in part, 76-77 and 80 in the reply filed on June 28, 2004 is acknowledged. The traversal is on the ground that since groups I and III are both in class 548 and groups II and IV-V are all in class 514, no serious burden for the examiner to search all the groups together. This is not found persuasive because please note that it was clearly delineated in the restriction requirement that *a subclass can not be identified without* a species election. Please note that class 548 has 969 subclasses and class 514 has 975 subclasses. To allege that searching all the inventions of class 548 or 514 is not a burden is just self evidenced that such demand is unreasonable burden.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 75 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims must under modern claim practice stand alone to define invention and incorporation into claims by express reference to specification is not permitted except in very limited circumstances. Ex parte Fressola 27 USPQ2d 1608.

Instant claims 75 and 77 employed example numbers from the specification for which each example is a compound and can be named with the IUPAC nomenclature or by structural delineation. There is no good reason why compounds can not be claimed by its name or structure. It is recommended that the names or structure of each compound be explicitly incorporated into the claims.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 72-74, 75 in part, 76-77 and 80 are *provisionally* rejected under 35 U.S.C. 102(e) as being anticipated by Magal SN 09/159,105 the national stage prosecution of WO 99/14998.

The relevant pages of WO 99/14998 is attached herewith. The current continuation pending application corresponding to SN 09/159,105 which is the priority of the WO 99/14998 would constitute a 102(e) reference upon issuance. See anticipatory compounds disclosed on pages 218-220 as attached and the priority benefit *prior* to the provisional date of the instant application.

This is a provisional rejection because the national stage application have not in fact been issued.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(f) he did not himself invent the subject matter sought to be patented.

Claims 72-74, 75 in part, 76-77 and 80 are rejected under 35 U.S.C. 102(f) as being anticipated by compounds disclosed on pages 218-220 and compositions (p.24-27) of WO 99/14998.

Please note that the WO 99/14998 patent disclosed compositions and identical compounds with “different” inventorship and “different” assignee. The evidence raised the issue that applicants are not the first to conceive and reduce to practice the invention since “another” was in possession of all the claimed species of compounds (compare ‘998 compounds 722, 794-812 vs instant compounds 4, 76-94 of claim 77) and reduced it to practice.

5. Please note that an enormous number of references have been recited on PTO-1449 which have been given a cursory review in accordance with the form as they are presented.

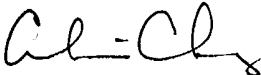
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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 1, 2004


Celia Chang
Primary Examiner
Art Unit 1625